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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,108	04/06/2000	Kenneth Eliot Sherman		7634

7590 01/24/2007

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/544,108	SHERMAN, KENNETH ELIOT	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,10-17 and 19-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,3-6 and 25* is/are allowed.

6)☒ Claim(s) *7,8,10-17,19-24 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed October 25, 2006 in response to the Office Action of June 13, 2006 is acknowledged and has been entered. Claims 3-6 have been amended. New claims 25 and 26 have been added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

Rejection of claims 1, 7, and 16 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is withdrawn.**

Applicant amended the claims to recite particular fragments of thymosin and the specification provides a representative number of species of thymosin (see page 13), thus the current specification and the claims comply with the written description requirement. For this reason the rejection is withdrawn.

Claim Rejections - 35 USC § 103

Rejection of claims 7, 8, 10-17, 19-24 under 35 U.S.C. 103(a) as being unpatentable over Huang et al. (of record in IDS of May 6, 2002) in view of Hoofnagle et al. (of record in IDS of May 6, 2002) and further in view of Horecker (US Patent 4,614,731) **is maintained.**

Applicant's arguments have been fully considered but are not persuasive. Applicant argues that Huang's composition is intended for treatment of Hepatitis B rather than Hepatitis C, as currently claimed. It is noted that the method claims are not subject to an art rejection. The currently rejected claims are drawn to a composition taught by Huang et al. It is noted that the intended use of the composition such as in the method of treatment of hepatitis B is not given

patentable weight. In a product claim, it is not essential to state the intended use and such intended use language is not afforded patentable weight. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant argues that Huang does not disclose what type of interferon is used. The full text article of the previously cited abstract by Huang does disclose a specific type of interferon such as the currently claimed alpha interferon (see page 71, last paragraph). Thus Huang teach the claimed composition. For this reason the rejection is maintained.

Rejection of newly added claim 26

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al. (Virologica Sinica, 1990, Vol. 5, p. 69-73) in view of Hoofnagle et al. (of record in IDS of May 6, 2002) and Horecker (US Patent 4,614,731) as applied to claims 7, 8, 10-17, 19-24 and further in view of Moody (US Patent 5,273,963).

Claims are drawn to a composition comprising an interferon-α and a fragment of thymosin selected from the group consisting of C-terminal 4-28, C-terminal 1-8, N-terminal 1-14 and N-terminal 1-20.

Claims 7, 8, 10-17, 19-24 have been rejected being unpatentable over Huang in view of Hoofnagle and Horecker. Huang teaches the composition comprising interferon alpha and thymosin. Hoofnagle teaches recombinant interferon-α for treatment of HCV infection and

Horecker teaches that thymosin fraction 5 (TF5) is effective in increasing T cell numbers and normalizing the immune function. Neither of references teach particular thymosin fragments recited in claim 26.

Moody teaches the currently claimed thymosin fragments, such as C-terminal 4-28, C-terminal 1-8, N-terminal 1-14 and N-terminal 1-20 fragment and their significance for therapeutic use (see column 6, lines 17-21). Thus, at the time when the current invention was made the thymosin fragments that have therapeutic significance, such as C-terminal 4-28, C-terminal 1-8, N-terminal 1-14 and N-terminal 1-20 have been known in the art.

It would have been obvious to one of ordinary skill in the art to use Moody's thymosin fragments in the composition of Huang.

One would have been motivated to use the thymosin fragments such as C-terminal 4-28, C-terminal 1-8, N-terminal 1-14 and N-terminal 1-20, in the composition comprising thymosin and alpha interferon, because Moody teaches that these particular thymosin fragments have been identified to have therapeutic significance.

One would have had a reasonable expectation of success to use particular thymosin fragments in Huang's composition because those thymosin fragments have been identified and made available to one of ordinary skill in the art at the time the current invention was made.

Conclusion

The reference, Huang et al. (Virologica Sinica, 1990, Vol. 5, p. 69-73), is currently being translated into English. Once the translation is complete, a copy will be mailed to Applicant in a supplemental action that will reset Applicant's period for response.

Applicant's amendment necessitated the new ground of rejections presented in this Office action. Thus, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B Chen 1/22/07

STACY B. CHEN
PRIMARY EXAMINER

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.

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